

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### A Study of The effect of infiltrative ketorolac on pain relief after hemorrhoidectomy

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Study aim

Determining the effect of topical ketorolac on pain control after hemorrhoidectomy

Last update: **2021-09-30, 1400/07/08**

Update count: **0**

#### Design

Two-way blind randomized clinical trial with parallel groups of two to three phases on 84 patients using numerical rating scale (NRS) using SPSS software version 21.

#### Registration date

2021-09-30, 1400/07/08

#### Settings and conduct

In this double-blind study, 84 patients with hemorrhoidectomy will attend Ali Ibn Abitalieb Hospital in Rafsanjan.

#### Registrant information

##### Name

Negin Shahrokhzadeh kermani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3429 8129

##### Email address

neginshahrokhzadeh@yahoo.com

#### Participants/Inclusion and exclusion criteria

Entry requirements for ages 15 to 55, ASA I-II Absence: Patients with Coagulation diseases and patients with a history of gastrointestinal bleeding or peptic ulcer and drug-related patients with a history of uncontrolled diabetes and hypertension and patients who have not received the drug in the 8 hours before surgery.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Intervention groups

Intervention group 1: At the end of the surgery, 4 cc of half a percent marcaine and 1 cc of ketorolac are infiltrated at the surgery site. Intervention group 2: At the end of the surgery, 4 cc of half a percent marcain is injected at the surgical site and 1 cc of ketorolac is injected at the same time. Intervention group 3: At the end of the surgery, 4% of the markain is infiltrated by half a percent at the surgical site.

#### Expected recruitment start date

2021-05-01, 1400/02/11

#### Expected recruitment end date

2021-11-02, 1400/08/11

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Main outcome variables

Pain score, pain measurement time, received medication, age, sex

#### Scientific title

A Study of The effect of infiltrative ketorolac on pain relief after hemorrhoidectomy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210922052556N1**

Registration date: **2021-09-30, 1400/07/08**

##### Public title

The effect of infiltrative ketorolac on pain relief after hemorrhoidectomy

##### Purpose

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
ASA I - II patients 15 to 55 years of age

**Exclusion criteria:**  
Patients with coagulation diseases Patients with a history of gastrointestinal bleeding or a history of gastrointestinal ulcers Drug-dependent patients Patients with a history of diabetes and uncontrolled hypertension Patients who received opioid for pain control 8 hours before surgery.

**Age**  
From **15 years** old to **55 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **84**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In this study, each participant is given a unique code that analyzes the data and participants are unaware of which group the assigned code belongs to.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
Participants in this study are divided into three intervention (case) groups.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

کمیته اخلاق دانشکده علوم پزشکی رفسنجان

##### Street address

Imam Ali St. Ali Ibn Abitaleb Hospital

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7717933777

#### Approval date

2021-01-29, 1399/11/10

#### Ethics committee reference number

IR.RUMS.REC.1399.242

## Health conditions studied

### 1

#### Description of health condition studied

Hemorrhoids

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Intensity of pain

#### Timepoint

Immediately after hemorrhoidectomy and 6 hours after hemorrhoidectomy and 12 hours after hemorrhoidectomy and 24 hours after hemorrhoidectomy

#### Method of measurement

Using NRS (pain rating system from 0 to 10)

## Secondary outcomes

### 1

#### Description

Medication received

#### Timepoint

Immediately after hemorrhoidectomy and 6 hours after hemorrhoidectomy and 12 hours after hemorrhoidectomy and 24 hours after hemorrhoidectomy

#### Method of measurement

View

## Intervention groups

### 1

#### Description

Intervention group 1: At the end of the surgery, 4 cc of half a percent marcaine and 1 cc of ketorolac are infiltrated at the surgery site.

#### Category

N/A

### 2

#### Description

Intervention group 2: At the end of the surgery, 4 cc of half a percent marcain is injected at the surgical site and 1 cc of ketorolac injected at the same time.

#### Category

N/A

### 3

#### Description

Intervention group 3: At the end of the surgery, 4% of the markain is infiltrated by half a percent at the surgical site.

#### Category

N/A

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Ali Ibn Abitaleb Hospital in Rafsanjan

###### Full name of responsible person

Negin Shahrokhzadeh Kermani

###### Street address

Ali Ibn Abitaleb Hospital ,Imam Ali Blvdlvd.

###### City

Rafsanjan

###### Province

Kerman

###### Postal code

7717966996

###### Phone

+98 34 3429 8129

###### Email

neginshahrokhzadeh@yahoo.com

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Rafsanjan University of Medical Sciences

###### Full name of responsible person

Ali Shamsizadeh

###### Street address

Imam Ali Boulevard, Rafsanjan University of Medical Sciences

###### City

Rafsanjan

###### Province

Kerman

###### Postal code

7717966996

###### Phone

+98 34 3429 8129

###### Email

AliShamsy@gmail.com

###### Grant name

###### Grant code / Reference number

###### Is the source of funding the same sponsor organization/entity?

Yes

###### Title of funding source

Rafsanjan University of Medical Sciences

###### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

### Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Negin Shahrokhzadeh Kermani

##### Position

Resident anesthesia

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Anesthesiology

##### Street address

No. 16 Laleh Ave.

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7717966996

##### Phone

+98 34 3429 8129

##### Email

neginshahrokhzadeh@yahoo.com

### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Negin Shahrokhzadeh Kermani

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Resident anesthesia

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Negin Shahrokhzadeh Kermani

**Position**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available